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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/700,548	11/05/2003	Laurence Gerald Hughes	Q78134	6075

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EXAMINER	
AZPURU, CARLOS A	
ART UNIT	**PAPER NUMBER**
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	04/11/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/700,548	HUGHES ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *16 January 2007*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *39-90* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *39-90* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Receipt is acknowledged of the amendment filed 01/16/2007.

The following rejections are maintained in this action:

Claim Rejections - 35 USC § 102

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (e) the invention was described in a patent granted on an application for patent by another filed in the United States before the invention thereof by the applicant for patent, or on an international application by another who has fulfilled the requirements of paragraphs (1), (2), and (4) of section 371(c) of this title before the invention thereof by the applicant for patent.

The changes made to 35 U.S.C. 102(e) by the American Inventors Protection Act of 1999 (AIPA) and the Intellectual Property and High Technology Technical Amendments Act of 2002 do not apply when the reference is a U.S. patent resulting directly or indirectly from an international application filed before November 29, 2000. Therefore, the prior art date of the reference is determined under 35 U.S.C. 102(e) prior to the amendment by the AIPA (pre-AIPA 35 U.S.C. 102(e)).

Claims 39-48, 52-56 are rejected under 35 U.S.C. 102(e) as being anticipated by Porssa et al.

The applied reference has a common assignee with the instant application. Based upon the earlier effective U.S. filing date of the reference, it constitutes prior art under 35 U.S.C. 102(e). This rejection under 35 U.S.C. 102(e) might be overcome either by a showing under 37 CFR 1.132 that any invention disclosed but not claimed in the reference was derived from the inventor of this application and is thus not the invention "by another," or by an appropriate showing under 37 CFR 1.131.

Porssa et al disclose a polymer formed from the combination of a zwitterionic monomer, a cationic monomer, and a hydrophobic termonomer (see Abstract), a coated stent thereof, and a method of coating the stent with said polymer. The new terpolymer has formulae: disclosed at col. 2,lines 21-67 and include YBX, Y B Q, and Y B Q. Substituents are defined just as they in the instant claims (see cols. 4-7 for the definitions of each). A coating process is set out in claims 17-25, while the polymer coating is set out in claims 1-16. While the disclosure of Porssa et al is silent as to the thickness of the coating once dry, the identical polymer is used to coat a stent in the same process steps. As such, the resulting coating would inherently have the same dry thickness. As such, the instant claims are clearly anticipated by Porssa et al.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the

invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

Claims 49-76, 83-88, and 90 are rejected under 35 US 103(a) as being unpatentable over Porssa et al further in view of both WO-A-98/15575 (WO'575) and US Pat No. 5,674,192 (US'192).

Porssa et al disclose a polymer formed from the combination of a zwitterionic monomer, a cationic monomer, and a hydrophobic termonomer (see Abstract), a coated stent thereof, and a method of coating the stent with said polymer. The new terpolymer has formulae: disclosed at col. 2,lines 21-67 and include YBX, Y B Q, and Y B Q. Substituents are defined just as they in the instant claims (see cols. 4-7 for the definitions of each). A coating process is set out in claims 17-25, while the polymer coating is set out in claims 1-16. While the disclosure of Porssa et al is silent as to the thickness of the coating once dry, the identical polymer is used to coat a stent in the same process steps. Porssa et al further disclose drug delivery at col. 6, line 63. Specific delivery of proteins and nucleic acids is not set out.

However, delivery of sense and antisense DNA from stents is set out in WO'5575. US '192 not only discloses delivery of nucleic acids, but monoclonal antibodies (proteins) from a hydrogel coating of a stent. As such, the ordinary practitioner would have found it well within his or her skill to use the disclosed coating of Porssa et al for drug delivery as suggested therein, and further, to specifically delivery both nucleic acids and proteins as suggested by WO'575 and US'192. These ordinary

practitioners would have further expected similar therapeutic benefits from the delivery of such agents given the teachings of Porssa et al in view of both WO'575 and US'192. As such, the instantly claimed delivery of either nucleic acids or proteins would have obvious at the time of invention given the disclosures of Porssa et al in view of both WO'575 and US'192.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 39-90 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 1-84 of copending Application No. 10,842,416 (US'416) in view of WO'575 and US'192.

US'416 disclose a method of coating an implant such as a stent using the instantly claimed polymers, addition steps, evaporation, and coating thickness. US'416 is silent as to the specific drugs which may be delivered using this coating.

However, delivery of sense and antisense DNA from stents is set out in WO'5575. US '192 not only discloses delivery of nucleic acids, but monoclonal antibodies (proteins) from a hydrogel coating of a stent. As such, the ordinary practitioner would have found it well within his or her skill to use the claimed coating of US'416 for drug delivery as suggested therein, and further, to specifically delivery both nucleic acids and proteins as suggested by WO'575 and US'192. These ordinary practitioners would have further expected similar therapeutic benefits from the delivery of such agents given the claimed coating US'416 in view of both WO'575 and US'192. As such, the instantly claimed delivery of either nucleic acids or proteins would have obvious at the time of invention given the claims of US'416 in view of both WO'575 and US'192.

This is a provisional obviousness-type double patenting rejection.

Response to Arguments

Applicant's arguments filed 01/16/2007 have been fully considered but they are not persuasive.

Applicant argues that Porssa disclose a polymer coating solution of 10 mg/ml, in contrast to the 50 mg/ml disclosed in Example 1 of the instant application. Applicant goes on to argue that the this higher concentration is significant because it corresponds to the greater thickness of polymer as well as a higher level of drug uptake. This data is then used to show the significance of the thickness of claim 1 providing beneficial results.

However when reviewing the other examples of the instant application, it is noted that all the other examples seem to have a drug concentration far below that of example 1. For example, in Example 2, polymer concentration is 25 mg/ml. Example 3 has a concentration of 20 mg/ml. Therefore, if the concentration as disclosed by Example 1 is critical to achieving a beneficial effect through formation of a minimum coating thickness, it is questioned how this is achieved at the lower polymer concentrations of Examples 2 and 3. Applicant's arguments are not persuasive and the rejection under 35 USC 102(e) is hereby maintained. The rejection of claims 57-69 and 70-82 and 89 however is withdrawn.

With regard to the rejection under 35 USC 103(a) applicant argues that both secondary references (US'192 and WO'575) involve delivery of different drugs into the vessel walls rather than the circulation. However, the references were merely used to show that delivery form stents of these drugs is well known. Inclusion of these drugs into the invention disclosed by Porssa would have been well within the skill of the ordinary practitioner. Further, applicant is arguing a limitation not found in the claims when setting out the different delivery of the references, since the instant claims are directed to a method of producing an implant, not a method of delivery.

Applicant again argues the criticality of the claimed thickness, however as noted above, applicant's own specification and examples would seem to contradict applicant's arguments.

With regard to the rejection under the judicially created doctrine of obviousness-type double patenting, applicant uses the specification to point out differences in the claimed polymers. However, upon review of the claims it must be pointed out that the claimed polymer would have been well within the skill of the ordinary practitioner according to the limitations found therein. As such the rejection is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Carlos A. Azpuru
Primary Examiner
Art Unit 1615

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